DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 33-36, in the reply filed on July 31, 2008 is acknowledged.

Applicant argues that:

1) Submitting a search and examination of all claims may be made without imposing a serious burden on the Examiner.

2) A search directed to a method of inhibiting the growth of pathogenic strains in the gastrointestinal tract of a human in need thereof comprising administering pediocin-producing pediococci to said human would be coextensive with a search for an isolated pediocin-producing pediococcus.

3) An important advantage in pursuing just one application encompassing all of the invention groups cited by the Examiner is that the examination work of the U.S. Patent and Trademark Office would be simplified, insofar as duplication of searching effort would be eliminated.

4) Clarification of the restriction requirement is requested. The Office action listed four groups, but the Examiner initially refers to "Groups I-VIII".

Applicant's arguments have been fully considered and are deemed non-persuasive.

With regard to Points 1-3, the special technical feature has been identified as *pediococcus*. Lindblom et al. (WO 97/29645) disclose an animal feed additive that comprises *Pediococcus acidilactici* (see abstract). Consequently, allowing the

separation of the four distinct inventions. Moreover, Applicant is arguing burden, however burden is not a criteria under 35 U.S.C. 121 and 372 or PCT Rule 13.1.

With regard to Point 4, the Examiner inadvertently typed I-VIII; the groups should be listed as "Groups I-IV", as evidenced by the listing of Groups I-IV in the paragraph that follows. The Examiner regrets the oversight.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17- 38 are pending. Claims 17-32, 37 and 38 have been withdrawn from further consideration as being drawn to non-elected inventions. Claims 1-16 have been canceled. Claims 33-36 are currently under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 17, 2006 is in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The disclosure is objected to because of the following informalities: A Brief Description of Figures has not been included in the specification.

Appropriate correction is required.

Claim Objections

4. Claim 34 is objected to because of the following informalities: The claim uses a trademark to identify the instant invention. Trademarks are not permissible in a claim. Appropriate correction is required.

5. Claim 34 is objected to because of the following informalities: on first recitation the acronym "BCCM" and "LMG" should be followed by its meaning, for example, "Belgian Coordinated Collections of Microorganisms". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 34 is drawn to an isolated pediocin-producing pediococcus characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%, wherein the pediococcus is *Pediococcus acidilactici* as deposited at BBCM/LMG under NO. LMG P-21927.

Because it is not clear that cell lines possessing the properties of ***Pediococcus acidilactici* LMG P-21927** are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above ***Pediococcus acidilactici* LMG P-21927**, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

There is no referral in the specification to provide a sufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon

public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As well as a statement that removes restrictions to provide access to this strain upon granting of a patent has not made, either in the instant Specification, nor in Applicant's Remarks.

One of the critical conditions of Deposit is defined in 37 CFR 1.808 requires that the deposit of biological material be made under two conditions: (A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (B) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent. Upon making this statement, the rejection under 35 USC 112, first paragraph will be withdrawn. This

rejection can be obviated through perfection of the Deposit and amendment of the claims to clearly set forth the Deposited strains.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the ***Pediococcus acidilactici*** **LMG P-21927** described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 33, 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated pediocin-producing pediococcus characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%.

The claims are drawn to a vast genus of pediocin-producing pedicoccus characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

The specification describes the pediocin-producing *Pediococcus acidilactici* as deposited at BCCM under accession number LMG P-21927. This strain of bacteria meets the written description requirements. However, the instant claims are encompass every pediocin-producing *Pediococcus acidilactici* with the recited functional characteristics. Since the specification is silent with regard to every other isolated *pedicoccus* strain that is characterized by a survival rate as per the Survival Rate Test

none of these strains meet the written description requirements. Moreover, the skilled artisan cannot envision every isolated *pedicoccus* strain that is characterized by a survival rate as per the Survival Rate Test. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The particular strain itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of the claimed pediocin-producing *pediococcus*, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of the pediocin-producing *pediococcus*, the skilled artisan could not immediately recognize or distinguish members of the claimed genus having been characterized by a survival rate of at least 90%. Therefore, because the art is unpredictable, in accordance with the Guidelines, the description of a pediocin-producing *pediococcus* is not deemed representative of the genus of a pediococcus to which the claims refer and hence do not meet the written description requirements.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is rendered vague and indefinite by the use of the phrase "characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%". It is unclear what is meant by said phrase, as it is not explicitly defined in the

specification. What constitutes being "characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 34 is rendered vague and indefinite by the use of the phrase "*Pediococcus acidilactici* as deposited at BCCM™/LMG under NO. LMG P-21927". It is unclear what is meant by said phrase as no structural or biological properties are conveyed by said phrase. What constitutes "BCCM™/LMG under NO. LMG P-21927"? Are they accession numbers or some other type of laboratory designation? If the former is true, Applicant is reminded that the claims must specifically recite the depository and the accession number under which the claimed organism was deposited. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 33, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindblom et al. (WO 99/11247).

The rejected claims are drawn to an isolated pediocin-producing pediococcus characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%.

Lindblom et al. disclose a composition that comprises *Pediococcus acidilactici,* characterized in that it comprises bacteriocins from Pediocin A, Pediocin AcH and *P. acidilactice* PAC 1.0 (see pages 3-4, line 32-34, 1, 20 and 21, respectively). Moreover, Lindblom et al. disclose that the composition has an effect on animals having normal bacterial flora and animals having pathological bacterial flora (see page 5, lines 16-19).

The *Pediococcus acidilactici* of Lindblom et al., absent evidence to the contrary, is the same and is necessarily a pediocin-producing Pediococcus having a survival rate of at least 90% as per the Survival Rate Test.

10. Claims 33, 35 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Samuelsson et al. (U.S. 2004/0253217 A1).

The rejected claims are drawn to an isolated pediocin-producing pediococcus characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%.

Samuelsson et al. disclose the use of novel isolated bacterial strains of the genus *Lactobacillus* and *Pediococcus* which have an ability to colonize and become established in a human vagina (see paragraph 0025). Samuelsson et al. disclose the

use of the strain of *Pediococcus acidilactici* (see paragraph 0028). Moreover, Samuelsson et al. disclose that it is preferable to use a combination of different bacterial species (see paragraph 0041).

The *Pediococcus acidilactici* strain of Samuelsson et al., absent evidence to the contrary, is the same and is necessarily a pediocin-producing Pediococcus having a survival rate of at least 90% as per the Survival Rate Test.

11. Claims 33, 35 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Laulund (U.S. 2002/0022019 A1).

The rejected claims are drawn to an isolated pediocin-producing pediococcus characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%.

Laulund discloses a medicament for reducing adverse changes of the gastrointestinal micro flora comprising a wide range of probiotically active microorganisms selected from Lactobacillus, Bifidobacterium, and Pediococcus among others (see abstract and paragraph 0033). Laulund discloses the use of *Pediococcus acidilactici* (see paragraph 0036). Moreover, Laulund discloses that the invention comprises the use of a combination of two or more of the probiotically active organisms (see paragraph 0037).

The *Pediococcus acidilactici* strain of Laulund, absent evidence to the contrary, is the same and is necessarily a pediocin-producing Pediococcus having a survival rate of at least 90% as per the Survival Rate Test.

12. Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Erkkila et al. (Meat Science, 2000; 55: 297-300).

The rejected claims are drawn to an isolated pediocin-producing pediococcus characterized by a survival rate as per the Survival Rate Test defined herein of at least 90%.

Erkkila et al. disclose the use of *Pediococcus acidilactici* (see abstract and Table 2-page 299). The *Pediococcus acidilactici* strain of Erkkila et al., absent evidence to the contrary, is the same and is necessarily a pediocin-producing Pediococcus having a survival rate of at least 90% as per the Survival Rate Test.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
10/8/08

/Robert A. Zeman/

for Lakia J. Tongue, Examiner of Art Unit 1645

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